

Remarks

Upon entry of the amendments, claims 1, 10-13, 15-20, 26-27, 31-50, 53-56, 63 and 68-80 will be pending. Claims 2-9, 14, 21-25, 28-30, 51-52, 57-62, and 64-67 are canceled herein without prejudice or disclaimer. Applicants reserve the right to prosecute the subject matter of these claims in later-filed continuation or divisional applications.

Claim 1 has been amended herein to more particularly point out and distinctly claim Applicants' invention. The amendment is solely made for purposes of expediting prosecution of this application. Support for the amendment can be found throughout the claims as filed (*e.g.*, at least claims 2, 14, 25, and 64).

Claims 10-13, 15-20, 26-27, 31, 34, 36-40, 47-49, 56, 63, 68, and 75-78 have been amended for clarity and to correct dependency, antecedent basis, and typographical errors.

Claim 18 has been further amended to recite heparin and methotrexate. Support for these limitations can be found in claim 30 as filed.

Claims 19 and 20 have been further amended to recite a step in the method. Support for these limitations can be found at least at page 9, lines 7-10 in the specification as filed.

Claim 68 has been amended to incorporate various limitations of claim 64, which is now canceled.

Claims 77 and 78 have been further amended for clarity. Support for these amendments can be found throughout the specification (*e.g.*, at least at page 26, lines 12-29).

Thus, no new matter is presented in these amendments.

Traversal of Restriction Requirement and Provisional Election of Group 16 directed to SEQ ID NO:24

In response to the requirement for restriction to a single inventive Group, Applicants provisionally elect Group 16 directed to the peptide of SEQ ID NO:24 with traverse. Claims 1, 6-13, 15-18, 26-27, 31-38, 53, 68-75, and 77-78, as amended, are readable thereon.

Peptides, Methods of Making, and Methods of Using

According to the Examiner, each of 171 separate groups is distinct because they fail to form a single general inventive concept under PCT Rule 13.1. *See* Office Action at page 2. The Examiner concludes that because the groups correspond to either a peptide sequence, or a

method of making or using the peptide, Applicants must elect a single invention under 37 C.F.R. § 1.499. *See id* at pages 2 and 7. Applicants traverse and present arguments herein that the claims to the products, and methods of making and using them, should all be examined together.

Applicants have herein amended the claims such that they are now directed to a product (*i.e.*, a penetrating module comprising specific penetrating peptides coupled to an effector, encompassed by claims 1, 6-13, 15-18, 26-27, 31-38, 53, 68-75, and 77-78 (Groups 1-21)), processes for making the product (encompassed by claims 39-50, 56, 76, and 79-80 (Groups 43-63, Groups 127-147, and Groups 151-171)), and methods of using the product (encompassed by claims 19-20, and 54-55 (Groups 22-42, and Groups 106-126)). A requirement to elect a single invention under 37 C.F.R. § 1.499 may be levied only where the application lacks a unity of invention according to 37 C.F.R. § 1.475. Under § 1.475(b)(3), an application will be considered to have unity of invention if the claims are drawn to a product, processes for the making the product, and uses of the product. Applicants contend that the claims as amended have a unity of invention since they are directed to a product, processes for making the product, and uses of the product. Thus, reconsideration and withdrawal of the restriction requirement is respectfully requested.

Notwithstanding the above, if the Examiner does not accept the grounds of traversal presented herein, Applicants reserve their right to rejoinder of the process claims pursuant to MPEP § 821.04 upon notification of an allowable product claim.

Peptide Sequences

The Examiner further requires that Applicants select one peptide to embody one invention with all the amino acids clearly indicated for the sequence. *See* Office Action at page 7. Applicants have provisionally elected SEQ ID NO:24 with traverse.

Applicants have amended claim 1, from which all remaining claims directly or indirectly depend, to recite a penetrating module comprising, in relevant part, a penetrating peptide comprising at least one amino acid sequence selected from the group consisting of SEQ ID NOS: 1-15 and 24-29. Applicants submit that the recited peptides (SEQ ID NOS: 1-15 and

24-29) share a similar function and are members of the same genus (penetrating peptides), and are related as described and claimed in the instant specification. Specifically, the disclosed penetrating peptides use conserved peptide sequences from various proteins involved in parocytosis to facilitate the translocation of an effector across a biological barrier. *See* specification at page 7, lines 11-12; and page 13, lines 9-11. Furthermore, a combination of such penetrating peptides may be used in the penetrating module of the instant invention.

Applicants assert that SEQ ID NOS: 1-15 and 24-29 do share a special technical feature within the meaning of PCT Rule 13.2, thereby fulfilling the unity of invention requirements of PCT Rule 13.1. Moreover, Applicants are permitted to include a reasonable number of dependent claims, which claim specific forms of the invention claimed in an independent claim under PCT Rule 13.4.

Conclusion

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. Should any questions or issues arise concerning this application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

With no extension of time this response is due on or before November 18, 2005. The Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 24348-501 NATL.

Respectfully submitted,



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